Docket No.: 080623-0349 PATENT

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of : Customer Number: 41552

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VANDERVEEN, TIMOTHY W., et al. : Confirmation Number: 9475

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Application No.: 10/750,345 : Tech Center Art Unit: 3767

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Filed: December 31, 2003 : Examiner: Deanna K. Hall

For: MEDICATION SAFETY ENHANCEMENT FOR SECONDARY INFUSION

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I hereby certify that this correspondence is being electronically-transmitted to the United States Patent and Trademark Office on <u>June 26, 2009.</u>
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# **REPLY BRIEF**

Sir:

The following Remarks are respectfully submitted in response to the Examiner's Answer dated April 28, 2009, pursuant to 37 C.F.R. § 41.41. Appellants reassert all arguments contained in the Principal Brief.

#### **ARGUMENTS**

1. Neither U.S. Pat. No. 6,213,972 ("Butterfield") nor U.S. Pat. No. 5,087,245 ("Doan"), whether alone or in combination, suggests a processor programmed to store a baseline pressure value in a memory, compare the baseline pressure value with pressure values sampled at a latter time, and if the latter sampled pressure value equals or is greater than a selected threshold pressure value, provide an alert that a fault condition exists.

Independent Claim 1 recites "a processor programmed to ... store [a] baseline pressure value in [a] memory, compare the baseline pressure value with pressure values sampled at a latter time, and if the latter sampled pressure value equals or is greater than a selected threshold pressure value, provide an alert that a fault condition exists." Independent Claim 8 recites a "processor programmed to ... store [a] baseline pressure value in [a] memory, ... compare the baseline pressure value with pressure values sampled after operating the pump to increase the pressure in the primary infusion line, and if the latter sampled pressure value equals or is greater than a selected threshold pressure value, provide an alert that a fault condition exists."

Remaining independent Claim 16 recites "storing [a] baseline pressure in a memory; ... comparing a characteristic of the pressure signals sampled after the pressure in the primary infusion line is increased with a characteristic of the threshold pressure; and providing an alert if the characteristic of the pressure signals is greater than or equal to the characteristic of the threshold pressure."

The Examiner has not shown that either Butterfield or Doan, whether alone or in combination, teaches or suggests at least these features of the independent claims.

### The Examiner's Position:

The Examiner contends that Butterfield at col.6 ll.15-27 discloses a processor 30 responsive to signals provided by a pressure sensor to establish a baseline pressure value and

provide an alert 40 that a fault condition exists. The Examiner also contends that Butterfield at col.4 ll.25-53 discloses a processor 30 that can sample pressure signals after operating a pump to compare these values with a baseline pressure value to provide an alert. Examiner's Answer, p.4.

Butterfield at col.6 ll.15-27 discloses a "processor 30 [that] compares monitored pressure values against a pressure threshold. If the monitored pressure ... exceeds the pressure threshold, the alarm system 40 will be activated." Butterfield at col.4 ll.25-53 discloses a "processor [that] applies different resistance measurement techniques depending on [a] selected flow rate."

The Examiner concedes that Butterfield does not disclose a memory for storing pressure related values, but contends that Doan teaches a memory 26 for storing pressure related values. The memory 26 of Doan is used "for receiving and storing … values generated in calculating the equilibrium pressure level" of a patient receiving an "infusion of parenteral fluid from a parenteral fluid delivery system." *See* Doan, col.5 ll.36-41.

## Appellants' Position:

The Examiner has not shown any suggestion in either Butterfield or Doan of "a processor programmed to ... store [a] baseline pressure value in [a] memory, compare the baseline pressure value with pressure values sampled at a latter time, and if the latter sampled pressure value equals or is greater than a selected threshold pressure value, provide an alert that a fault condition exists," as recited in independent Claim 1. The Examiner has also not shown any suggestion in either Butterfield or Doan of a "processor programmed to ... store [a] baseline pressure value in [a] memory, ... compare the baseline pressure value with pressure values sampled after operating the pump to increase the pressure in the primary infusion line, and if the latter sampled pressure

value equals or is greater than a selected threshold pressure value, provide an alert that a fault condition exists," as recited in independent Claim 8. The Examiner has further not shown any suggestion in either Butterfield or Doan of "storing [a] baseline pressure in a memory; ... comparing a characteristic of the pressure signals sampled after the pressure in the primary infusion line is increased with a characteristic of the threshold pressure; and providing an alert if the characteristic of the pressure signals is greater than or equal to the characteristic of the threshold pressure," as recited in independent Claim 16.

The Examiner has not shown where Butterfield or Doan suggests comparing a stored baseline pressure value with a pressure value sampled at a later time. In col.6 ll.23-30 of Butterfield, the processor 30 compares a current monitored pressure value to a predetermined pressure threshold, but does not compare the current monitored pressure value to a previously stored instance of the monitored pressure value. ("The processor 30 compares monitored pressure values against a pressure threshold .... In a preferred embodiment, the pressure threshold is 600 mm Hg.").

Doan does not anywhere suggest the comparison of a stored baseline pressure value with a pressure value sampled at a later time, nor does the Examiner contend that Doan suggests this feature of the independent claims.

#### **CONCLUSION**

A rejection under 35 U.S.C. § 103 in view of a prior art reference can be properly sustained if the references either expressly or impliedly suggest the claimed invention. MPEP Section 706.02(j); Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

The burden imposed on the Examiner by 35 U.S.C. § 103 as stated in the above-identified precedent has not been and further cannot be discharged because, as demonstrated above, the Examiner has not established that either Butterfield or Doan, whether alone or in combination, suggests "a processor programmed to ... store [a] baseline pressure value in [a] memory, compare the baseline pressure value with pressure values sampled at a latter time, and if the latter sampled pressure value equals or is greater than a selected threshold pressure value, provide an alert that a fault condition exists," as recited in independent Claim 1, a "processor programmed to ... store [a] baseline pressure value in [a] memory, ... compare the baseline pressure value with pressure values sampled after operating the pump to increase the pressure in the primary infusion line, and if the latter sampled pressure value equals or is greater than a selected threshold pressure value, provide an alert that a fault condition exists," as recited in independent Claim 8, or "storing [a] baseline pressure in a memory; ... comparing a characteristic of the pressure signals sampled after the pressure in the primary infusion line is increased with a characteristic of the threshold pressure; and providing an alert if the characteristic of the pressure signals is greater than or equal to the characteristic of the threshold pressure," as recited in independent Claim 16. Accordingly, prima facie obviousness of independent Claims 1, 8, and 16 has not been established by the Examiner.

The remaining applied reference, U.S. Pat. No. 5,032,112 ("Fairchild") does not remedy the foregoing deficiencies of Butterfield and Doan. Fairchild was cited for allegedly teaching a

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check valve disposed between a primary container and the connection of a secondary infusion

line to a primary infusion line. Examiner's Answer, p.5. However, Fairchild does not suggest at

least the above-identified features of the independent claims, nor does the Examiner contend

Fairchild suggests these features.

Accordingly, based upon the foregoing arguments and the previously submitted Appeal

Brief, Appellants respectfully submit that the outstanding rejection under 35 U.S.C. § 103(a) of

Claims 1-11 and 16-19 is not legally viable. Appellants therefore respectfully solicit the

Honorable Board to reverse the Examiner's rejection of Claims 1-11 and 16-19.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is

hereby made. Please charge any shortage in fees due in connection with the filing of this paper,

including extension of time fees, to Deposit Account 502624 and please credit any excess fees to

such deposit account.

Respectfully submitted,

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